REMARKS/ARGUMENTS

Status of the Claims

Claims 69 and 71 were rejected. Claims 1-68, 70, and 72-75 have been withdrawn from consideration as being drawn to non-elected inventions and have been canceled without prejudice or disclaimer. Moreover, the subject matter of claim 69 has been incorporated into claim 71 to expedite prosecution, and, therefore, claim 69 has also been canceled. Applicants reserve the right to file a continuation or divisional application or to take other such appropriate action to seek protection of the canceled claims.

Claim 71 has been amended to more clearly define the invention. Support for the claim amendments can be found at, for example, paragraphs [0001], [00034], [00036], [00042], and [00045], and in Figures 12 and 19. New claims 76-80 have also been added. Support for these newly submitted claims can be found in the specification and claims as originally filed. See, for example, original claims 3-7 and paragraphs [00034], [00036], [00042], and [00045]. No new matter has been added by way of the claim amendments or the submission of new claims 76-80.

Claims 71 and 76-80 are now pending in the present application. Reexamination and reconsideration of these claims are respectfully requested in view of the claim amendments and the following remarks. The Examiner's comments in the Office Action are addressed below in the order set forth therein.

The Objections to the Specification Should Be Withdrawn

The specification was objected to for use of the trademark name "Accuspray." The specification has been amended such that each reference to "Accuspray" is capitalized and followed by a proper trademark symbol (i.e., ACCUSPRAY™), as required by MPEP 608.01(v). No new matter has been added by way of these amendments. In light of the amendments to the specification, the objection has been obviated and should be withdrawn.

The Objection to Claim 71 Should Be Withdrawn

Claim 71 was objected to for incorrect spelling of the term "staphylococcal." Applicants appreciate the Examiner bringing this error to their attention. Claim 71 has been amended to

correct this typographical error, thereby obviating the objection to the claim. In light of the claim amendment, the Examiner is respectfully requested to withdraw the objection to the claim.

The Rejection of the Claims Under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn

Claims 69 and 71 were rejected under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claims the subject which Applicants regard as the invention. In particular, the Examiner has asserted that claim 69, the subject matter of which has been incorporated into amended claim 71, is indefinite for use of the term a "therapeutic" agent in the context of the claimed vaccine. Applicants respectfully disagree with the Examiner's assertion that a vaccine is "by definition…prophylactic [and] not therapeutic" (page 3, Office Action mailed January 25, 2007). One of skill in the art would appreciate that a "vaccine" includes compositions designed to treat and not just to prevent the development of a particular disease, as the Examiner contends. Therapeutic vaccines, particularly in the fields of AIDS and cancer research, are currently under development. The Examiner herself has cited U.S. Patent No. 6,251,385, which is directed to a cancer vaccine, and U.S. Patent Application Publication No. 2006/0024322, which discloses a vaccine for the treatment of certain autoimmune disorders. See pages 5-7, Office Action mailed January 25, 2007. Therefore, in light of the above remarks and the Examiner's own statements, Applicants respectfully request that the rejection of claim 71 as indefinite be withdrawn.

The Rejection of the Claims Under 35 U.S.C. § 102 Should Be Withdrawn

As a preliminary matter, Applicants note that original claim 69, but not claim 71, was rejected under 35 U.S.C. §§ 102(b) and 102(e) as being anticipated by Ahmed *et al.* (1994) *Microbiol. Immunol.* 38:837-842, U.S. Patent No. 6,251,385, U.S. Patent Application Publication No. 2003/0186271, and/or U.S. Patent Application Publication No. 2003/0180755. See points 6, 7, 9, and 10 at pages 3-6 and 8-10 of the present Office Action. Claim 71, however, was not rejected as being anticipated by *any* of the above references. In light of the cancellation of claim 69, Applicants respectfully submit that the above-referenced rejections under 35 U.S.C. §§

102(b) and 102(e) have been obviated and should be withdrawn. Accordingly, these rejections have not been addressed here in detail.

Claims 69 and 71 were further rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2006/0024322 (hereinafter the "'322 patent publication"). As described above, claim 69 has been canceled. This rejection is respectfully traversed with respect to claim 71.

Amended claim 71 is directed to a particulate recombinant Staphylococcal enterotoxin B (rSEB) vaccine composition made by a method comprising atomizing a liquid rSEB formulation to produce an atomized formulation, freezing the atomized rSEB formulation to form solid particles, and drying the particles to produce discrete dried particles of the rSEB vaccine composition. Support for amended claim 71 can be found in the specification and the claims as originally filed. As described in the specification and shown in, for example, Figures 12 and 19, the resultant dried particles are discrete powder particles that lie generally within particular particle size ranges. See, for example, paragraphs [0034], [0036], [0042], and [0045] of the instant application. Accordingly, claim 71 and new claims 76-80 now expressly recite that the final product comprises discrete dried particles of the rSEB vaccine composition.

The '322 patent publication discloses a Staphylococcal enterotoxin B (SEB) vaccine, particularly a solid vaccine formulation produced by *lyophilization*. See paragraph [0048] of the cited reference. In contrast to the discrete dried vaccine particles described in the specification and recited in the present claims, the desired end product of lyophilization is a "cake" and not a collection of discrete particles. See, for example, "*Lyophilization: Introduction and Basic Principles*" (Thomas A. Jennings, ed.; Interpharm Press 1999), portions of which are submitted herewith for the Examiner's consideration. Therefore, contrary to the Examiner's assertions, the '322 patent publication does not teach the discrete dried rSEB vaccine particles of claim 71.

A *prima facie* case of anticipation under 35 U.S.C. § 102 has not been established. According to the Federal Circuit, "anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). The '322 patent publication teaches a

lyophilized SEB vaccine product. In contrast to the claimed rSEB vaccine composition, however, the cited reference does not teach or suggest producing the discrete dried vaccine particles of the present invention. The lyophilization process taught by the '322 patent publication and generally known in the art would produce a "cake" of the SEB vaccine and simply would not result in the discrete dried particles produced by atomizing a liquid rSEB vaccine formulation to produce an atomized formulation, freezing the atomized rSEB formulation to form solid particles, and drying the particles to produce discrete dried rSEB vaccine particles, as recited in amended claim 71. The physical structure of the lyophilized vaccine disclosed by the '322 patent publication, or *any* lyophilized vaccine, differs from that of the *discrete* dried rSEB vaccine particles of claim 71. Specifically, Applicants note that the process steps recited in the claim "would be expected to impart distinctive structural characteristics to the final product" when compared to those of the lyophilized vaccine taught by the '322 patent publication. *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). *The end products made by lyophilization are not the same as those produced by the method steps of claim 71.*

As the Examiner correctly remarks, the patentability of product-by process claims such as claim 71 is judged by reference to the *end product* itself and not by the method used to produce the final product. See also MPEP 2113. Here, the lyophilized SEB vaccine "cake" taught by the '322 patent publication is simply not the same as the particulate rSEB vaccine composition of claim 71, for the reasons set forth above. Although the product of the cited reference may "appear to be the same as the product claimed," Applicants respectfully submit that they have satisfied their burden of establishing that the claimed rSEB vaccine composition is not the same as the lyophilized SEB vaccine taught by the cited reference (page 7, Office Action mailed January 25, 2007). Accordingly, the reference does not teach each and every element of claim 71 and, therefore, does not anticipate the present invention. Applicants respectfully request that the rejection of claim 71 under 35 U.S.C. § 102(e) in view of the '322 patent publication be withdrawn and not applied to newly submitted claims 76-80, all of which depend from independent claim 71.

CONCLUSION

The Examiner is respectfully requested to withdraw the rejection of claim 71 and and to not apply the rejection to new claims 76-80. In view of the above remarks and the claim amendments, it is submitted that this application is now ready for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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